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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,642	02/22/2002	Robert J. Fitzsimmons	24004350.10022US	8163

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PATENT DEPARTMENT
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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,642	FITZSIMMONS, ROBERT J.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-7) in the reply filed on 7 October 2004 is acknowledged. The traversal is on the ground(s) that the Inventions of Group I and Group II are not necessarily distinct. This is not found persuasive because Group I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the device of Group II produces an electromagnetic field. This device may be used to disrupt radio transmissions, sort paramagnetic materials, and/or as a component in an alternator (to generate electricity). Claims **8-17** are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7 October 2004. The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims **1-7** of this application. Provisional Application 60/271030 does not contain any teachings of stimulating VEGF receptors using electromagnetic waves.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: duration, pulse period, and frequency.
4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term “biological effect” in claim 6 is a relative term which renders the claim indefinite. The term “biological effect” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear from the Specification or the prior art as to what the metes and bounds of a “biological effect” are in terms of the invention.
6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites the limitation “predetermined” in the first line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 5, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Aaron *et al.* (April 1989) "Stimulation of experimental endochondral ossification by low-energy pulsing electromagnetic fields." J Bone Miner Res. 4(2): 227-33.
8. Aaron *et al.* (1989) teaches a method of studying the effect of pulsing electromagnetic fields (PEMF) on the extracellular matrix and calcification of endochondral ossification *in vivo* thus meeting the limitations of claims 1 and 2 (Figures 1 and 2). Aaron *et al.* teaches that the synthesis of cartilage, the subsequent endochondral calcification, and the maturation of bone trabeculae (which includes cell growth) are all enhanced by exposure to a PEMF thus meeting the limitations of claims 5, 6, and 7 (Figures 3-6).
9. The Examiner notes that the Specification teaches an embodiment of exposing bones cells *in vivo* to an electromagnetic field (pp. 3). Thus, Aaron *et al.* is practicing the method of claims 1 and 2 since the chondrocytes and bones cells have VEGF receptors. Aaron *et al.* also reports a biological activity, ossification, commensurate with VEGF activation by a ligand thus meeting the limitations of claims 5 and 6 (Tables 1 and 2).

10. Claims 1, 2, 5, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sollazzo *et al.* (1997) "Responses of Human MG-63 Osteosarcoma Cell Line and Human Osteoblast-Like Cells to Pulsed Electromagnetic Fields." Bioelectromagnetics 18(8): 541-547.
11. Sollazzo *et al.* (1997) teaches a method of treating MG-63 cells and human osteoblast-like cells to pulsed electromagnetic fields (PEMF) which induces cell proliferation (Tables 2-7).
12. The Examiner notes that the Specification includes an example using MG-63 cells and exposing them to an electromagnetic field (pp. 12). Thus, Sollazzo *et al.* is practicing the method of claims 1 and 2 since the MG-63 cells have VEGF receptors. Sollazzo *et al.* also reports a biological activity, cell growth commensurate with VEGF activation by a ligand thus meeting the limitations of claims 5, 6, and 7 (Figure 2).
13. Claims 1, 2, 5, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by De Mattei *et al.* (1999) "Correlation between pulsed electromagnetic fields exposure time and cell proliferation increase in human osteosarcoma cell lines and human normal osteoblast cells in vitro." Bioelectromagnetics 20(3): 177-82.
14. De Mattei *et al.* teaches a method of exposing cultured bone cells (TE-85, MG-63, and human normal osteoblast cell NHOC) to a pulsed electromagnetic field (PEMF) at 1.3-ms pulse, repeated at 75 Hz for different periods of time (Tables 2-5). De Mattei *et al.* used H³-Thymidine incorporation to measure cell proliferation.
15. The Examiner notes that the Specification includes an example using MG-63 cells and exposing them to an electromagnetic field (pp. 12). Thus, De Mattei *et al.* is practicing the

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method of claims 1 and 2 since the MG-63 cells have VEGF receptors. De Mattei *et al.* also reports a biological activity, cell growth commensurate with VEGF activation by a ligand thus meeting the limitations of claims 5, 6, and 7 (Figures 2-3).

16. Claims 1, 2, 5, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,100,373 (31 May 1992) Liboff *et al.*

17. US '373 teaches a method of exposing a rabbit model of osteoporosis to an electromagnetic field and then measuring the effects of the electromagnetic field on the recovery of the rabbit bone cells thus meeting the limitations of claims 1 and 2 (Tables II).

18. The Examiner notes that the Specification explicitly states an embodiment of the claimed invention to be treatment of osteoporosis via exposure to an electromagnetic field (pp. 3). Thus US '373 is practicing the method of claims 1 and 2 since the bone cells have VEGF receptors as implied by the Specification. US '373 also reports mineralization and callus formation as signs of recovering from osteoporosis and is therefore commensurate with VEGF activation by a ligand thus meeting the limitations of claims 5, 6, and 7 (Col. 21-24).

19. Claims 1, 3, 4, 5, 6, and 7 are rejected under 35 U.S.C. 102(a)/102(e) as being anticipated by US 6,334,069 (25 December 2001) George *et al.*

20. US '069 teaches a method of exposing primary human fibroblasts to an electromagnetic field which stimulates their proliferation (Example 3). This includes vascular and/or endothelial cells thus meeting the limitations of claim 3 (Col. 19-20).

21. US '069 also teaches said method wherein the frequency ranges from 1000 Hz to 1000 MHz thus meeting the limitations of claim 4 (Col. 9).
22. The Examiner notes that the Specification explicitly states an embodiment of the claimed invention to be increased cell proliferation via exposure to an electromagnetic field (pp. 3 and claim 7). Thus US '069 is practicing the method of claims 1 and 2 since the fibroblasts have VEGF receptors as implied by the Specification and is therefore commensurate with VEGF activation by a ligand thus meeting the limitations of claims 5, 6, and 7 (Col. 1-2).
23. Claims 1, 2, 3, 5, 6, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,561,968 B1 (13 May 2003) Dissing *et al.*
24. US '968 teaches a method of promoting bone growth and/or angiogenesis by means of an electromagnetic field thus meeting the limitations of claims 1 and 2 (Col. 10; 17; 22-24). This includes vascular and/or endothelial cells thus meeting the limitations of claim 3 (Col. 19-20).
25. The Examiner notes that the Specification explicitly states an embodiment of the claimed invention to be increased bone cell and vascular endothelial cell proliferation via exposure to an electromagnetic field (pp. 3 and claim 7). Thus US '968 is practicing the method of claims 1 and 2 since the fibroblasts and bone cells have VEGF receptors as implied by the Specification and is therefore commensurate with VEGF activation by a ligand thus meeting the limitations of claims 5, 6, and 7 (Col. 1-2).

Summary

26. No Claims are allowed.

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27. The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon for the instant rejection(s) are considered pertinent to the instant application:

- a. US 6,733,435 B2 (11 May 2004) Cañedo
- b. US 6,364,824 B1 (2 April 2002) Fitzsimmons

Conclusion

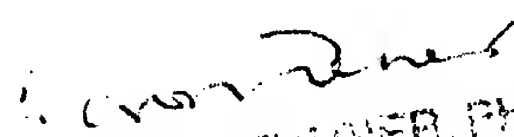
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

December 13, 2004


SHARON L. TURNER, PH.D.
PATENT EXAMINER
12-15-04